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68-7-25. Notification to board; pharmacist, pharmacy technician, or pharmacy intern.

Each pharmacist, pharmacy technician, and pharmacy intern shall notify the board in writing of any of the following circumstances within 30 days of the date of occurrence:

- (a) Any conduct resulting in a charge of, arrest or indictment for, plea of guilty or no contest to, diversion agreement, or suspended imposition of sentence against the registrant or licensee that would constitute any of the following:
 - (1) Unprofessional conduct as defined by K.S.A. 65-1626, and amendments thereto;
 - (2) a violation of the federal or state food, drug, and cosmetic act; or
 - (3) a violation of the Kansas uniform controlled substances act;
 - (b) any conviction of any felony against the registrant or licensee; or

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68-20-15b. Notification to board; suspected diversion, theft, or loss of controlled substances. Either the pharmacist-in-charge or the pharmacy owner shall notify the board in writing within one day of any suspected diversion, theft, or loss of any controlled substance and, upon completion, shall provide the board with a copy of the completed DEA 106 form issued by the U.S. department of justice. (Authorized by K.S.A. 2017 Supp. 65-4102; implementing K.S.A. 65-4117; effective P-________.)

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Kansas Administrative Regulations Economic Impact Statement For the Kansas Division of the Budget

Kansas Board of Pharmacy Agency

Alexandra Blasi Agency Contact 785-296-8419 Contact Phone Number

<u>68-2-23, 68-20-15b, 68-7-25</u> K.A.R. Number(s)

Submit a hard copy of the proposed rule(s) and regulation(s) and any external documents that the proposed rule(s) and regulation(s) would adopt, along with the following to:

Division of the Budget
900 SW Jackson, Room 504-N
Topeka, KS 66612

I. Brief description of the proposed rule(s) and regulation(s).

K.A.R. 68-2-23 is a new regulation that would require each owner of a Kansas-registered pharmacy to notify the board within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy, the pharmacy owner, or any application, license, registration, or permit held by the pharmacy owner.

K.A.R. 68-20-15b is a new regulation that would require either the pharmacist-in-charge or the owner of any Kansas-registered pharmacy to notify the board in writing within one day of any suspected diversion, theft, or loss of any controlled substance and provide a copy of the completed DEA-106 form.

K.A.R. 68-7-25 is a new regulation that would require each pharmacist, pharmacy technician, and pharmacy student to notify the board within 30 days of any criminal arrest, charge, or conviction rationally related to drugs or the practice of pharmacy, or any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against any professional or occupational application, license, registration, or permit held by the individual.

II. Statement by the agency if the rule(s) and regulation(s) is mandated by the federal government and a statement if approach chosen to address the policy issue is different from that utilized by agencies of contiguous states or the federal government. (If the approach is different, then include a statement of why the Kansas rule and regulation proposed is different)

The regulations are not mandated by the federal government. This approach is consistent with notification requirements for the majority of state boards of pharmacy, the National Association of Boards of Pharmacy model act, and other Kansas regulatory agencies.

III. Agency analysis specifically addressing following:

A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

The regulations should not have any impact on business growth. Pharmacy activities may be impacted slightly by the notification requirements associated with the facilities, but only if the triggering factual scenarios occur. Impact is very minor.

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B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule and regulation and on the state economy as a whole;

Pharmacies may elect to update policy and procedure manuals or create a standardized format for reporting to the Board. Costs would be limited to the staff time associated with generating the required reports to the Board and responding to any resulting investigation initiated by the Board.

In the event of a loss or suspected theft/diversion of a controlled substance, the Board may initiate an investigation which may include an on-site inspection of the facility and its records. This may generate costs for the pharmacy in the form of staff time, but costs are difficult to estimate because they can vary greatly depending on the facts. Ultimately, a minor loss is unlikely to result in financial impact, whereas a major diversion of controlled substances could include a lengthy investigation and potential disciplinary action, including a fine of up to \$5,000 per violation of the pharmacy practice act.

No other economic impact is anticipated.

C. Businesses that would be directly affected by the proposed rule and regulation;

Pharmacies, Hospitals, and other facilities that employ licensed pharmacists and registered students or technicians.

D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;

The benefit is significant because these regulations allow the Board to receive more timely notification of situations that may constitute a violation of the Kansas pharmacy practice act or the controlled substance act. Currently, the Board only receives information at the time of renewal unless the individual or facility elects to notify the Board. By receiving more timely notification, the Board can investigate and initiate necessary disciplinary action sooner, thereby more readily protecting Kansas citizens.

E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

K.A.R. 68-2-23 and 68-7-25 allow 30 days for notification to the Board. This is longer than some agencies (10-15 days) and provides a more reasonable timetable for licensees.

K.A.R. 68-20-15b requires an immediate notification to the Board, but then allows time for the pharmacy to complete their investigation into the suspected theft, loss, or diversion and merely provide a copy to the Kansas Board of the document already prepared for the federal government (DEA-106). This avoids duplication of efforts.

F. An estimate, expressed as a total dollar figure, of the total annual implementation and compliance costs that are reasonably expected to be incurred

by or passed along to business, local governments, or

members of the public.

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\$0

An estimate, expressed as a total dollar figure, of the total implementation and compliance costs that are reasonably expected to be incurred by or passed along to business, local governments, or members of the public.

\$0

Do the above total implementation and compliance costs exceed \$3.0 million over any two-year period?

YES □ NO ⊠

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

Many pharmacies and licensees are already engaged in this practice to comply with other state and federal laws. Costs of implementation are negligible because of the current tracking systems and requirements already in existence in pharmacies. Free options are available to licensees for notification to the Board (email, fax, in person).

Prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing if the total implementation and compliance costs exceed \$3.0 million over any two-year period to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.

YES \square NO \boxtimes

G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

No impact.

H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

The Board consulted other state boards of pharmacy, other Kansas regulatory boards, and the National Association of Boards of Pharmacy to craft these requirements. Board staff (licensed pharmacists) also reviewed the requirements. No public impact is anticipated.

I. For environmental rule(s) and regulation(s) describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

Not environmental.

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